4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Sixth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Sixth Annual Sentinel Initiative." Convened by the Engelberg Center for Health Care Reform at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an overview of the status of FDA's Sentinel Initiative and future plans, highlights from key Mini-Sentinel and related activities, and an update on active surveillance collaborations and program extensions. In addition, this workshop will engage stakeholders to discuss current and emerging Sentinel projects and facilitate stakeholder feedback and input on Sentinel projects that would be appropriate to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action (e.g., labeling changes, postmarketing requirements (PMRs), or postmarketing commitments (PMCs)). This workshop satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

Date and Time: The public workshop will be held on January 14, 2014, from 9 a.m. to 4 p.m.

Location: The public workshop will be held at the Washington Marriott at Metro Center, 775 12th Street, NW., Washington, DC 20001. For additional travel and hotel information, please refer to http://www.cvent.com/d/jcqhyy. (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register).

Contact Person: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6358, Silver Spring, MD 20993, 301-796-3714, FAX: 301-847-3529, email: SentinelInitiative@fda.hhs.gov.

Registration: To attend the public workshop, you must register before January 14, 2014, by visiting http://www.cvent.com/d/jcqhyy. Early registration is recommended. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. There is no registration fee for the public workshop; but because seating is limited, registration will be on a first-come, first-served basis. A 1-hour lunch break is scheduled; however, food will not be provided. There are multiple restaurants within walking distance of the hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (email: jKlatzman@brookings.edu) at least 7 days in advance.

Meeting Materials: All event materials will be available to registered attendees via email prior to the workshop and will be posted after the event on the Brookings Institution event Web site at http://www.brookings.edu//health/events.

Transcripts: Please be advised that transcripts will not be available.

SUPPLEMENTARY INFORMATION:

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144). Title I of FDASIA reauthorizes PDUFA and provides FDA with the user fee resources necessary to maintain an efficient review process for human drug and biological products. The reauthorization of PDUFA includes performance goals and procedures for the Agency that represent FDA's commitments during fiscal years 2013-2017 (PDUFA V). These commitments are fully described in the document entitled "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017" (PDUFA Goals Letter), available on FDA's Web site at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf. Section XI of the PDUFA Goals Letter, entitled "Enhancement and Modernization of the FDA Drug Safety System," includes Sentinel as a tool for evaluating drug safety issues that may require regulatory action. As part of this enhancement, FDA committed to hold a public meeting to engage stakeholders in a discussion of current and emerging Sentinel projects and facilitate stakeholder feedback and input to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action, e.g., labeling changes, PMRs, or PMCs. The public workshop announced by this notice will fulfill this commitment.

Dated: November 5, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013-26855 Filed 11/07/2013 at 8:45 am; Publication Date: 11/08/2013]